3.2.6 AFCEE Requirements for Risk Characterizations in Human Health Risk Assessments

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Introduction

Risk characterization is the final component of a human health risk assessment. It integrates information from the preceding hazard identification, toxicity assessment, and exposure assessment components of the risk assessment, then generates an overall conclusion about risk and the related uncertainties that is complete, informative, and useful for the risk managers. The risk characterization conveys the risk assessors' professional judgments about the nature and existence of—or lack of—human health risks (U.S. EPA, 1995). Both the human health and ecological risk assessment require characterizations. The risk characterizations for human health risk assessments are developed and presented independently from the ecological risk assessments that are performed for a site.

Although it is the final step in risk assessment, risk characterization is the starting point for risk management considerations and the foundation for remedial decision-making. Because every risk assessment involves many assumptions, and therefore has many uncertainties, the challenge in characterizing risk is to convey the subset of findings, strengths, and limitations of the risk assessment that are key for the risk managers.

Effective risk management is impeded without effective communication of information about the receptors potentially at risk, how these receptors might be affected, what the severity and reversibility of adverse effects might be, how confident the risk assessors are in their predictions, and other qualitative information that is critical for decision-making. The objective is to relay to the risk manager(s)—in frank terms—the scope, strengths, and limitations of the risk assessment.

AFCEE Requirements

The risk characterization will restate the scope of the assessment, express results clearly, articulate major assumptions and uncertainties, identify reasonable alternative interpretations, and separate scientific conclusions from regulatory agency policy considerations and requirements.

The risk characterization section will bring the toxicity/potency data and the exposure data together into quantitative expressions of estimated risk for all receptors considered in the risk assessment. Minimally, risk characterization of a human health baseline risk assessment will include the following:

1. Tables presenting reasonable maximum and central tendency estimates of exposure point concentrations for each chemical of potential concern (COPC) in each medium
2. Tables presenting the parameter values used to estimate both maximum and central tendency exposures parameter values for each exposure pathway

3. Tables presenting the cancer slope factors and reference doses, as well as the sources of these values, used to estimate risk and the hazard index for each COPC and exposure route
4. Tables presenting reasonable maximum and central tendency estimates of cumulative cancer risk and hazard indices arranged by receptors and exposure scenarios (current and future)
5. A table summarizing reasonable maximum and central tendency estimated pathway risks and hazard indices arranged by receptors and media clearly indicating the estimated risk from background concentrations and site concentrations of each relevant COPC
6. Tables identifying and explaining the noteworthy uncertainties associated with the quantified risks and hazards arranged by receptors and exposure scenarios (current and future)
7. Comprehensive statements of the quantified estimates of cancer risks and hazard indices that clearly address the likelihood that the risk may actually be realized by the receptors

The requirements of item number 7 include unequivocal statements of the key strengths and weaknesses of the assessment, a brief bottom line statement about the risks (including the confidence in the estimate[s] of risk and hazard indexes), and information on what is known about the nature, likelihood, and magnitude of any potential adverse effect (U.S. EPA, 2000). This information will be provided prominently, along with all statements that present the quantitative risk estimates.

Recommended Practices and Guidance

From the beginning of and throughout the risk assessment process, dialogue among the risk assessors and the risk assessment users will ensure that the risk assessors understand the needs of the decision makers. This type of collaboration will enable decision makers to produce a risk assessment that will completely and efficiently address their needs with results that can be communicated effectively to stakeholders who might be affected by the risk management decisions. While conducting a risk assessment, assessors should focus on the key points that need to be presented in the final risk characterization step.

The risk characterization of the baseline risk assessment should highlight the greatest potential sources of risk at a site so that they may be addressed effectively in the remediation process. One requirement of the risk characterization is that conclusions about the magnitude and kind of risk at a site be developed. Another requirement is that conclusions be developed on the likelihood that the estimated risk will actually be realized by the current or future receptors. However, the risk assessment should not include an evaluation of the significance of the risk in a program context or whether and how the risk should be addressed; these are risk management issues (U.S. EPA, 1989).

References

U.S. EPA. 1989. *Risk Assessment Guidance for Superfund, Volume 1: Human Health Evaluation Manual, Part A Baseline Risk Assessment, Interim Final (RAGS, Part A).* U.S. Environmental Protection Agency: EPA/540/1-89/002.

U.S. EPA. 1995. *Policy for Risk Characterization at the U.S. Environmental Protection Agency*. Issued by the Administrator of the U.S. Environmental Protection Agency (March).

U.S. EPA. 2000. "Risk Characterization," *Science Policy Council Handbook*. U.S. Environmental Protection Agency: EPA 100-B-00-002F.